Claims 7-22, 24 and 25 stand rejected under 35 U.S.C § 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. These claims are also rejected under 35 U.S.C. § 112, first paragraph, as failing to be adequately described in the specification adequately as filed.

The claimed subject matter is a full-length clone that encodes a secreted protein isolated from human stomach cancer.[1] The clone comprises 372 base pair open reading frame[2] encoding a 123 amino acid protein[3] that is sufficiently similar to chicken stem cell antigen 2 (L34554), and especially prostate stem cell antigen that those of ordinary skill expect it to share activity with this pse antigen.

In response, the Examiner states (1) Applicants' asserted utility is not specific, e.g., it is applicable to any naturally occurring polypeptide and (2) Applicants' statement (in the specification) that based on sequence similarity, the claimed protein and PSCA share at activity is insufficient; in other words, the Examiner points out Applicants do not demonstrate such function. Those points are addressed in turn.

As noted, the claims are rejected under 35 U.S.C. § 101 as not having a specific and substantial utility that is credible (USPTO Utility Examination Guidelines, 66 Fed. Reg. at 1098). In this regard, the Examiner necessarily contends (i) the activity of the present invention is not credible since (ii) those of ordinary skill recognize protein activity cannot be predicted from known homologous sequences. According to the Examiner,

satisfy the utility requirement of 35 USC 101

Specification page 46, line

page 46, line 24.

because, given the state of the art, structure-function analysis is unpredictable. This basis of rejection is, respectfully submitted, without foundation either in law or in fact.

The Examiner's point concerning the unpredictability of protein activity from known homologous sequences is not at all well-taken by those of ordinary skill. That is, while protein activity can, as noted by the Examiner, differ markedly upon minor changes, those of ordinary skill nevertheless reasonably expect to find such activity in homologous peptides. See, e.g., Principles of Protein Structure, Cantor, ed. (1978) 167 wherein it is explicitly taught that

> "[h]omologous proteins result from speciation or differentiation. Comparisons between homologous proteins have yielded general rules for protein structures (citing Schulz, Angew. Chem. Int. Edit., Vol. 16 (1977) 23-33). . . . In this context it is often useful to distinguish between protein speciation and protein differentiation (citing Molecular evolution and Polymorphism, Kimura ed. (1977) National Institute of Genetics, Mishima, Japan). Speciation is the evolution of homologous proteins possessing a common function in different organisms."

This knowledge is summarized in the art as evidencing that establishing homology between the unknown and reference proteins permits the skilled artisan to assume the unknown unexpressed protein and the known reference protein have the same function. Functional Genomics, Science, Vol. 278, No. 601 (1997).

This is not an aberrant position; similarly, the American Society of Human Genetics ("ASHG") similarly acknowledges "sequence homology is a useful predictor of gene function." Letter from Ronald Worton, Ph.D., President, ASHG, to the Honorable Q.

Trademarks, Unites States Patent and Trademark Office at 2 (Mar. 22, 2000) (on file with the USPTO).

Additionally, the USPTO too recognizes the state of this art in Example 10 of the Utility Training Materials: DNA fragments encoding a Full Open Reading Frame (ORF). In the example the Examiner is directed not to reject the claims merely because the applicant's asserted utility is premised on the "overall level of sequence similarity between SEQ ID NO:3 [the unknown sequence] and the consensus sequence of the known DNA ligases that are presented in the specification." Indeed, UTM Example 10 acknowledges that "homology between the known and unknown protein is sufficient to ascribe the known protein's function to the unknown; thus the claim possesses credible, substantial, and specific utility."[4] Id. at 54.[5]

Moreover, the PTO acknowledges as well utility is well-established if it is readily apparent to one skilled in the art. Id. at 55. This is in conformity with the law promulgated by the Federal Circuit, which notes 35 U.S.C. 112 can be satisfied even by "genus claims to nucleic acids based on their hybridization properties. . . . [if the subject matter of the claims will] hybridize under highly stringent conditions to known sequences because such conditions dictate that all species within the genus will be structurally

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[4] Although the Examiner disregards the homology noted between the clinical subject matter and the known proteins in the prior art as being irrelevant, such is plainly not the case. Indeed, the 90% homology seen in UTM Example 10 is exceeded by the 99.2% homology herein (see page 4 of the Official Action, last line).

[5] To the extent necessary, Applicants will promptly file a Declaration under Rule 132

[illegible] respectfully requested.

similar." Enzo Biochem v. Gen-Probe, Appeal No. 01-1230 slip op. granting reh'g at 15 (Fed. Cir. July 15, 2002).

See for instance, in In re Folkers, 145 USPQ 390 (CCPA 1965), where a new compound belonging to the known family of quinones and hydroquinones was alleged, without more, to have the electron transport activity of that known class. Id at 393. The predecessor court to the Federal Circuit held that function is inferred based on similarity to a substance with a known function. Id. Similarly, in In re Brana 34 USPQ 1436, 1442 (Fed. Cir. 1995), the Federal Circuit noted

> "[a]lthough it is true that minor changes in chemical compounds can radically alter their effects on the human body, evidence of success in structurally similar compounds is relevant in determining whether one skilled in the art would believe an asserted utility."

Applicants with to point out that, at the very least, the resemblance of the present invention to specific proteins of known activity makes it clear the present invention can be further utilized as research tools for better characterizing those prior art compounds. Regarding this point, that asserted utility, e.g., to better characterize prior art cadherins, is specific. That is, while specific utility excludes generalized research tools like probes, such is not so, however, when the target being probed for is already known. Revised Interim Utility Guidelines Training Materials at 50-53.[2]

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[2] In this regard, the PTO decided long ago that the ESTs must be rejected since use as research tools is not specific and they have insufficient homology to support a specific, substantial and credible utility. However, such logic (used in the context

Accordingly, respectfully submitted, the rejection under 35 U.S.C. § 101 is overcome and withdrawal thereof is earnestly solicited.

Claims 7-22 and 24-25 are also rejected under 35 U.S.C. § 112 first paragraph. In support of this rejection, the Examiner states that because the invention is not supported by a substantial asserted utility, one of ordinary skill would not know how to use it. However, as seen explained above, the present invention is supported by a specific and substantial utility.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 7-9, 13-19, 21 and 22 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

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Registration No. 31,865

[illegible] & SCINTO

VERSION WITH MARKINGS TO SHOW CHANGES MADE TO CLAIMS

10. (Cancelled)

11. (Cancelled)

12. (Cancelled)

13. (Amended) An isolated nucleic acid molecule [consisting] comprising a nucleotide sequence which is complementary to the nucleotide sequence of the nucleic acid molecule of any one of claims 7, 8[,] or 9[, 10, or 11].

14. (Amended) An isolated nucleic acid molecule comprising the nucleic acid molecule of any one of claims 7, 8[,] or 9[, 10, or 11], and a nucleotide sequence encoding a heterologous polypeptide.

15. (Amended) An isolated nucleic acid molecule of claims 7, 8[,] or 9[, 10, or 11], wherein said nucleic acid molecule is operably linked to at least one expression control sequence.

17. (Amended) A vector comprising the nucleic acid molecule of any one of claims 7, 8[,] or 9[, 10, or 11].

20. (Cancelled)

21. (Amended) An isolated polypeptide comprising [of] the amino acid sequence set forth in SEQ ID NO:1.

24. (Cancelled)